Attorney Docket No. A-67499-2/RMS/RMK/SPL Dorsey File No. 463037-292

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

*In re* application of:

Examiner:

To Be Assigned

Kayyem

Art Unit:

To Be Assigned

Serial No.:

To Be Assigned

Express Mail No: EV 29898105 US

Filing Date:

October 29, 2003

For:

TISSUE COLLECTION DEVICES

**CONTAINING BIOSENSORS** 

## INFORMATION DISCLOSURE STATEMENT AND STATEMENT OF RELATEDNESS

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicant wishes to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO-1449. Since copies of the references were provided either by the Applicant or the Examiner in the following related U.S. Application: Serial No.09/472,657, filed December 27, 1999, upon which the instant application relies for its priority date, in accordance with 37 C.F.R. § 1.98(d), no copies of these references are enclosed.

In addition, Applicant wishes to draw the attention of the U.S. Patent and Trademark

Office to the references cited, previously not disclosed in the following related U.S. Application

Serial No.09/472,657, filed December 27, 1999, on the accompanying form PTO-1449 marked with an asterisk (\*). Copies of the references are enclosed.

With respect to patent applications, the applicants point out their duty under M.P.E.P. §2001.06(b) to disclose relevant patent applications of which they are aware. To this end, the applicants draw the Examiner's attention to the following patent applications:

- 1. U.S.S.N. 08/873,978, filed June 12, 1998;
- 2. U.S.S.N. 09/577,577, filed April 21, 2000;
- 3. U.S.S.N. 09/135,183, filed August 17, 1998;
- 4. U.S.S.N. 08/873,597, filed June 12, 1997;
- 5. U.S.S.N. 09/452,277, filed February 3, 1999;
- 6. U.S.S.N. 09/245,105, filed January 27, 1999;
- 7. U.S.S.N. 09/096,593, filed June 12, 1998;
- 8. U.S.S.N. 10/016,416, filed December 10, 2001;
- 9. U.S.S.N. 09/295,691, filed April 21, 1999;
- 10. U.S.S.N. 09/238,351, filed January 27, 1999; and
- 11. U.S.S.N. 09/621,275, filed July 20, 2000.

None of the foregoing references is believed to disclose the invention as claimed.

Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application.

Submission of the present document shall not be construed as an admission that a search has

been made or that better art does not exist.

As far as is known to the undersigned, this Information Disclosure Statement is being

filed within three months of the filing date of a national application, within three months of the

date of entry of the national state in an international application, or before the mailing date of a

first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is

required.

While no fee is believed to be due, if this belief is in error the Commissioner is

authorized to charge any additional fees, including extension fees or other relief which may be

required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 463077-

292 [A-67499-2/RMA/JML]).

Please direct any calls in connection with this application to the undersigned at

(415) 781-1989.

Respectfully submitted,

DORSEY & WHITNEY LLP

Robin M. Silva, Reg. No. 38,304

Customer Number: 32940

Dated:

Dorsey & Whitney LLP

Intellectual Property Department

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Attachments:

Form PTO/SB/8A-B, Substitute for form PTO 1449

Nine (9) References

SF-1122725\_1

- 3 -

Substitute for form 1449A/PTO Complete if Known (Modified) To Be Assigned Application Number INFORMATION DISCLOSURE October 29, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Kayyem Group Art Unit To Be Assigned (use as many sheets as necessary) **Examiner Name** To Be Assigned 11 A-674992-2/RFT/RMS/RMK Sheet 1 of Attorney Docket Number

	U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	U.S. Patent Document Number-Kind Code <sup>2</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	A1	4,704,193	11-03-1987	Bowers et al.				
	A2	4,707,352	11-17-1987	Stavrianopoulos				
	A3	4,707,440	11-17-1987	Stavrianopoulos				
	A4	4,711,955	12-08-1987	Ward et al.	•			
	A5	4,755,458	07-05-1988	Rabbani et al.				
	A6	4,787,963	11-29-1988	MacConnell	-			
	A7	4,840,893	06-20-1989	Hill et al.				
	A8	4,849,513	07-18-1989	Smith et al.				
	A9	4,868,103	09-19-1989	Stavrianopoulos et al.				
	A10	4,894,325	01-16-1990	Englehardt et al.				
	A11	4,943,523	07-24-1990	Stavrianopoulos				
	A12	4,945,045	07-31-1990	Forrest et al.				
	A13	4,952,685	08-28-1990	Stavrianopoulos				
	A14	4,994,373	02-19-1991	Stavrianopoulos				
	A15	5,002,885	03-26-1991	Stavrianopoulos	-			
	A16	5,013,831	05-07-1991	Stavrianopoulos				
	A17	5,082,830	01-21-1992	Brakel et al.				
	A18	5,089,112	02-18-1992	Skotheim et al.				
	A19	5,175,269	12-29-1992	Stavrianopoulos				
	A20	5,180,968	01-19-1993	Bruckenstein et al.				
	A21	5,241,060	08-31-1993	Englehardt et al.				
	A22	5,242,828	09-07-1993	Bergstrom et al.				
	A23	5,278,043	01-11-1995	Bannwarth et al.				
	A24	5,312,527	05-17-1994	Mikkelsen et al.				
	A25	5,328,824	07-12-1994	Ward et al.				
	A26	5,356,786	10-18-1994	Heller et al.				
	A27	5,391,272	02-21-1995	O'Daly et al.				
	A28	5,403,451	04-04-1995	Riviello et al.				
	A29	5,436,161	07-25-1995	Bergstrom et al.				
	A30	5,443,701	08-22-1995	Willner et al.				
	A31	5,449,767	09-12-1995	Ward et al.				
	A32	5,472,881	12-05-1995	Beebe et al.				
	A33	5,476,928	12-19-1995	Ward et al.				
	A34	5,552,270	09-03-1996	Khrapko et al.				
	A35	5,565,552	10-15-1996	Magda et al.				

Examiner Date Considered		

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Substitute for form 1449A/PTO (Modified)			VPTO	Complete if Known		
				Application Number	To Be Assigned	
INFORMATION DISCLOSURE				Filing Date	October 29, 2003	
STATEMENT BY APPLICANT			PLICANT	First Named Inventor	Kayyem	
				Group Art Unit	To Be Assigned	
	(use as many sheets as necessary)			Examiner Name	To Be Assigned	
Sheet	2	of	11	Attorney Docket Number	A-674992-2/RFT/RMS/RMK	

•	U.S. PATENT DOCUMENTS							
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	A36	5,571,568	11-05-1989	Ribi et al.				
	A37	5,573,906	11-12-1996	Bannwarth et al.				
	A38	5,591,578	01-07-1997	Meade et al.				
	A39	5,595,908	01-21-1997	Fawcett et al.				
	A40	5,601,982	02-11-1997	Sargent et al.				
	A41	5,603,711	02-18-1997	Parins et al.				
	A42	5,607,646	03-04-1997	Okano et al.				
	A43	5,620,850	04-15-1997	Bamdad et al.				
	A44	5,632,957	05-27-1997	Heller et al.				
	A45	5,700,667	12-23-1997	Marble et al.				
-	A46	5,705,348	01-06-1998	Meade et al.				
	A47	5,741,700	04-21-1998	Ershov et al.				
	A48	5,756,050	05-26-1998	Ershov et al.				
	A49	5,770,369	06-23-1998	Meade et al.				
	A50	5,770,721	06-23-1998	Ershov et al.				
	A51	5,776,672	07-07-1998	Hashimoto et al.				
	A52	5,780,234	07-14-1998	Meade et al.				
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	A54	5,824,473	10-20-1998	Meade et al.				
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	A57	5,851,772	12-22-1998	Mirzabekov et al.				
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	A61	6,001,087	12-14-1999	Zurcher				
	A62	6,060,023	05-09-2000	Maracas				
	A63	6,060,327	05-09-2000	Keen				
	A64	6,071,699	06-06-2000	Meade et al.				
	A65	6,087,100	07-11-2000	Meade et al.				
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	A67	6,096,273*	08-01-2000	Kayyem et al.				
	A68	6,096,825	08-01-2000	Garnier et al.				
	A69	6,107,080	08-22-2000	Lennox				
	A70	6,177,250	01-23-2001	Meade et al.				

Examiner Signature	Date Considered		

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Substitute for form 1449A/PTO			VPTO	Complete if Kn wn		
(Modified)		Application Number	To Be Assigned			
INFORMATION DISCLOSURE				Filing Date	October 29, 2003	
S	(use as many sheets as necessary)			First Named Inventor	Kayyem	
				Group Art Unit	To Be Assigned	
				Examiner Name	To Be Assigned	
Sheet	3	of	11	Attorney Docket Number	A-674992-2/RFT/RMS/RMK	

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	A71	6,180,352	01-30-2001	Meade et al.				
	A72	6,200,761	03-13-2001	Meade et al.				
	A73	6,203,758	03-20-2001	Marks et al.				
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	A75	6,221,583*	04-24-2001	Kayyem et al.				
	A76	6,232,062*	05-15-2001	Kayyem et al.				
	A77	6,238,870	05-29-2001	Meade et al.				
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		F	OREIGN PATEN	T DOCUMENTS		
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	B1	CA 2 090904	09-1993	-		
	B2	DE 197 25 190	12-1998			
	ВЗ	EP 0 229943	07-1987		, , , <u>-</u>	
	B4	EP 0 234938 (A2)	02-1987			
	B5	EP 0 599337	01-1994	·		
	B6	EP 0 63879	11-2002			
	B7	EP 0515615	09-1996	·		
	B8	JP 238,166	1988		Abstract (63-238166)	
	B9	JP 6-41183	02-1994			
	B10	WO 85/05815	03-1985			
	B11	WO 90/05732	05-1990			
	B12	WO 92/10757	06-1992			
_	B13	WO 93/10267				
	B14	WO 93/22678	11-1993			
	B15	WO 93/23425	11-1993			
	B16	WO 94/22889	10-1994			

Examiner Signature	Date Considered
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	B17	WO 95/15971	06-1995			
	B18	WO 96/40712	12-1996			
·	B19	WO 96/40712	12-1996			
	B20	WO 97/01646	01-1997			
	B21	WO 97/27329	07-1997			$\top$
	B22	WO 97/31256	08-1997			
	B23	WO 97/41425	11-1997			
	B24	WO 97/44651	11-1997			
	B25	WO 98/20162	05-1998			
	B26	WO 98/20162	05-1998			
	B27 .	WO 98/27229	06-1998			
	B28	WO 98/27229	06-1998			
	B29	WO 98/28444	07-1998			
	B30	WO 98/35232	08-1998			
	B31	WO 98/51823	11-1998	,		
	B32	WO 98/57159	12-1998			
	B33	WO 98/57319	11-1999			$\Box$
	B34	WO 99/14596	03-1999			
	B35	WO 99/29711	06-1999			
	B36	WO 99/37819	07-1999	1		1
	B37	WO 99/67425	12-1999		·	

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Signature		Considered	

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Substitute for form 1449A/PTO Compl te if Known (Modified) To Be Assigned Application Number **INFORMATION DISCLOSURE** Filing Date October 29, 2003 STATEMENT BY APPLICANT First Named Inventor Kayyem Group Art Unit To Be Assigned (use as many sheets as necessary) **Examiner Name** To Be Assigned A-674992-2/RFT/RMS/RMK Sheet 5 11 Attorney Docket Number

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					
	C1	Affirm VP III, Microbial Identification Test, for in Vitro Diagnostic use, Catalog No. 4406252 (1996).					
	C2	AIZAWA et al., "Integrated Molecular Systems for Biosensors," Sensors and Acuators B, B@\$ (Nos 1/3) Part 1:1-5 (March 1995).					
	С3	ALBERS et al., "Design of Novel Molecular Wires for Realizing Long-Distance Electron Transfer," Biochemistry and Bioenergetics, 42:25-33 (1997).					
	C4	ALLEMAN, K.S. et al., "Electrochemical Rectification at a Monolayer-Modified Electrode," <i>J. Phys. Chem.</i> , 100:17050-17058 (1996).					
	C5	ARKIN et al. "Evidence for Photoelectron Transfer Through DNA Intercalation," <i>J. Inorganic Biochem. Abstracts</i> , 6th International Conference on Bioinorganic Chemistry, 51(1) & (2):526 (1993).					
	C6	"Biotechnology and Genetics: Genetic Screening Integrated Circuit," The Economist (February 25-March 3, 1995).					
	C7	BAMDAD, C. "A DNA self-assembled monolayer for the specific attachment of unmodified double - or single stranded DNA," Biophysical Journal, 75:1997-2003 (1988).					
	C8	BARISCI et al., "Conducting Polymer Sensors," TRIP, 4(9):307-311 (1996).					
	C9	BAUM, R. M., "Views on Biological, Long-Range Electron Transfer Stir Debate," C&EN, pp 20-23 (1993).					
	C10	BECHTOLD, R. et al., "Ruthenium-Modified Horse Heart Cytochrome c: Effect of pH and Ligation on the Rate of Intramolecular Electron Transfer between Ruthenium(II) and Heme(III)," J. Phys. Chem., 90(16):3800-3804 (1986).					
·	C11	BIDAN, "Electroconducting conjugated polymers: new sensitive matrices to build up chemical or electrochemical sensors. A Review.," Sensors and Actuators, B6:45-56 (1992).					
	C12	BLONDER et al., "Three-dimensional Redox-Active layered Composites of Au-Au, Ag-Ag and Au-Ag Colloids," Chem. Commun. 1393-1394 (1998).					
	C13	BOGUSLAVSKY, L. et al., "Applications of redox polymers in biosensors," Solid State Ionics, 60:189-197 (1993).					
	C14	BOWLER, B. E. et al., "Long-Range Electron Transfer in Donor (Spacer) Acceptor Molecules and Proteins," <i>Progress in Inorganic Chemistry: Bioinorganic Chemistry</i> , 38:259-322 (1990).					
	C15	BRODOLIN, K. et al., "Conformational changes in E.Coli RNA Polymerase During Promoter Recognition," Nucleic Acids Research, 24(24):5748-5753 (1993).					
	C16	BRUN, A. M. et al., "Photochemistry of Intercalated Quaternary Diazaaromatic Salts," J. Am. Chem. Soc., 113:8153-8159 (1991).					
	C17	BUMM, et al., "Are Single Molecular Wires Conducting?," Science 271:1705-1707 (1996).					
	C18	CANTOR, C.R. et al., "Report on the Sequencing by Hybridization Workshop," Genomics, 13:1378-1383 (1992).					
	C19	CARR et al., "Novel Electrochemical Sensors for Neutral Molecules," Chem. Commun., 1649-1650 (1997).					
	C20	CARTER et al., "Voltammetric Studies of the Interaction of Metal Chelates with DNA. 2. Tris-Chelated Complexes of Cobalt(III) and Iron(II) with 10-Phenanthroline and 2,2'-Bipyridine," J. Am. Chem. Soc., 11:8901-8911 (1989).	Γ				
	C21	CHANG, I-JY et al., "High-Driving-Force Electron Transfer in Metalloproteins: Intramolecular Oxidation of Ferrocytochrome c by Ru(2,2'-bpy)₂(im)(His-33)³*," <i>J. Am. Chem. Soc.</i> , 113:7056-7057 (1991).					

Examiner Signature	Date Considered	

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	(use as many she	ets as ne	cessary)	Examiner Name	To Be Assigned	
Sheet	6	of	11 ·	Attorney Docket Number	A-674992-2/RFT/RMS/RMK	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
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S	STATEMENT BY APPLICANT			First Named Inventor	Kayyem	
				Group Art Unit	To Be Assigned	
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				Group Art Unit	To Be Assigned	
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